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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/272,809	03/19/99	LAGARIAS J	23070-943

HM12/0711
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EXAMINER	
HINES, J	
ART UNIT	**PAPER NUMBER**
1645	18

DATE MAILED: 07/11/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/272,809	Lagarias
Examiner	**Art Unit**
Ja-Na Hines	1645

-- The MAILING DATE of this communication appears on the cover she t with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Jul 6, 1999

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-32 is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-32 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Drawings

1. The drawings are objected to because of the reasons set forth in the attached PTOL-948. Correction is required.

Specification

2. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

3. The disclosure is objected to because of the following informalities: The attempt to incorporate subject matter into this application by reference to http://www.kazusa.or.jp/cyano/ is improper because Applicants have embedded a hyperlink which is impermissible and requires deletion. This attempt to incorporate subject matter into the patent by reference is improper because PTO policy does not permit the PTO to link to any commercial sites since the PTO exercises no control over those organizations, views or accuracy of the information contained on those outside sites. Appropriate correction is required.

Claim Objections

4. Claims 7-8 are objected to because of the following informalities: Claim 7 uses the acronym sp, and Claim 8 uses Cph2 however, it has not been previously defined. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 5-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims refer to an apoprotein protein, however no apoprotein protein has been previously recited. It is unclear if protein and polypeptide are meant to be equivalent terms, however the claims should recite consistent language.

Claims 5 and 6 recites the limitation "the apoprotein protein" in the claims. There is insufficient antecedent basis for this limitation in the claim.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

6. Claims 1-3, 9-21 and 27-31 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4, 6-7, 9-11, 13-16, 19, 21-22 and 24-26 of U.S. Patent No. 6,046,014. Although the conflicting claims are not identical, they are not patentably distinct from each other because US Patent 6,046,014 has claims drawn to a composition comprising a phytochrome apoprotein and a bilin chromophore, where the apoprotein contains a chromophore domain; consist of the N-terminal domain; and has a bilin

which is a tetrapyrrole or phycoerythrobilin. The composition has a moiety which is a biomolecule wherein the biomolecule is selected from the group consisting of a protein or nucleic acid. The claims are also drawn to a method of detection the presence of a biomolecule where the apoprotein is selected from a group of apoproteins; the light has a wavelength of about 570nm or 590; the apoprotein polypeptide has a chromophore domain; and the bilin is tetrapyrrole or phycoerythrobilin. The method has a moiety which is a biomolecule wherein the biomolecule is selected from the group consisting of a protein, antibody or nucleic acid. The claims of the instant application are drawn to a composition comprising an apoprotein where the apoprotein contains a lyase domain which is equivalent to the chromophore domain of the US Patent; is the N-terminal domain; and has a linked bilin which is a tertrapyrrole or phycoerythrobilin. The composition has a biomolecule wherein the biomolecule is selected from the group consisting of a protein or nucleic acid. The claims are also drawn to a method of detection the presence of a biomolecule where the apoprotein is selected from a group of apoproteins; the light has a wavelength of about 570nm or 590; the apoprotein polypeptide has a lyase domain; and the bilin is tetrapyrrole or phycoerythrobilin. The method has a moiety which is a biomolecule wherein the biomolecule is selected from the group consisting of a protein, antibody or nucleic acid.

Therefore, the claims are conflicting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

7. Claims 1-3, 6-7, 9-22, 25 and 27-32 are rejected under 35 U.S.C. 102(e) as being anticipated by Lagarias et al., US Patent 6,046,014. Lagarias et al., teaches a new class of fluorescent proteins that are useable as fluorescent markers (col. 2 lines 63-65). These markers have the ability of long wavelength absorption maxima, high molar absorption coefficients and the ability of recombinant phytochrome apoproteins to spontaneously assemble with a variety of bilin chromophore precursors, and the phytochromes are ideal fluorescent markers (col. 2-3 lines 65-3). The protein component comprises an apoprotein component and a nitrogen heterocyclic component which can be a tetrapyrrole or the particularly preferred phycoerythrobilin (col. 3 lines 17-24). The apoprotein can be derived plants, green alga, or cyanobacteria or can be chemically synthesized (col. 3 lines 25-30). Figure 10 illustrates a phytochrome operon of *Synechocystis* species. Truncated apoproteins consisting of a chromophore domain and the apoprotein N-terminal subsequence sufficient for lyase activity are preferred (col. 3 lines 35-40). The chromophore domain refers to the apoprotein N-terminal subsequence sufficient for lyase activity (col. 5 lines 39-43). This domain of subsequences consist of preferable less than about 400 amino

acids (col. 3 lines 45-46) or even 390 or 350 amino acids (col. 5 lines 45-49). The fluorescent adduct can be covalently or noncovalenty linked to the label moiety (col. 3 lines 47-50). The moiety can be any composition such as a biomolecule, including proteins, carbohydrates, lipids, members of a binding pair and nucleic acids (col. 3 lines 50-65). This invention also provides methods of use for the fluorescent adducts (col. 4 lines 13-15). The method tests for the presence of a biomolecule in a sample comprising a biomolecule linked to a fluorescent adduct consisting of an apoprotein and a bilin chromophore and contacting the sample with light which causes the fluorescent adduct to emit light and detect the emitted light thereby detecting the presence of the biomolecule (col. 4 lines 13-23). The sample is contacted with light having a wavelength of about 570nm or about 590nm (col. 4 lines 25-29).

Prior Art

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Clack et al., teaches phytochrome apoprotein family in *Arabidopsis* is encoded by five genes. Lagarias et al., teaches the self-assembly of synthetic phytochrome holoprotein of plants requires a covalently bound linear tetrapyrrole, bilin, prosthetic group for its photoreceptor function. Li et al., (1992) teaches phytochrome assembly. Li et al., (1995) teaches the continuous fluorescent assay of phytochrome assembly *in vitro*. Terry et al., teaches the biosynthesis of the plant photoreceptor phytochrome.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines

May 29, 2001

5/29/01

JENNIFER E. GRASER
PRIMARY EXAMINER